

REMARKS

This application is believed to be amended in a manner to place it in condition for allowance at the time of the next Official Action.

Claims 1 and 11-24 are amended. Claims 27-29 are new. Support for claim 1 and the new claims may be found generally throughout the specification, particularly at page 4, line 1 to page 6, line 2. With respect to the amendment to claims 11-24, applicant does not disclaim any particular uses, pharmaceutical agents or pharmaceutical compositions, and the amendment is intended to be non-narrowing. Claim 10 is withdrawn from further consideration as being directed to a non-elected species. Claims 1-24 and 27-29 remain pending in the application and are believed to be readable on the elected invention and species.

The Official Action objects to the specification for not including sequence identifiers on page 9, 13 and 14. Applicant respectfully submits the Preliminary Amendment filed April 13, 2005 amending the specification at pages 9, 13 and 14 to add the sequence identifiers to these pages. Accordingly, applicant respectfully requests that the objection be withdrawn.

Claims 1-9 and 11-24 were objected to as encompassing non-elected sequences. Applicant understands that the claims currently recite non-elected subject matter.

Claims 1-9 were rejected under 35 U.S.C. 112, first paragraph, for not satisfying the enablement requirement. Applicant respectfully disagrees.

The Official Action states the claims meet the enablement requirement for SEQ ID NO: 8, but not any peptide comprising SEQ ID NO: 8. However, applicant respectfully submits that the peptides presently recited in claim 1, and new independent claims 27 and 29, are enabled by the present specification at page 4.

Therefore, applicant respectfully requests that the enablement rejection be withdrawn.

Claims 11-24 were rejected under 35 U.S.C. 112, first paragraph, for not satisfying the enablement requirement. Applicant respectfully disagrees.

The Official Action states that the claims are enabled for in vitro, not in vivo treatment. However, the present claims are directed to a composition comprising the recited peptide and pharmaceutically acceptable carriers. Applicant does not disclaim any particular uses, pharmaceutical agents or pharmaceutical compositions, and the amendment is intended to be non-narrowing. Accordingly, applicant believes that the claims 11-24, and new claim 28, do satisfy the enablement requirement, as the present invention discloses compositions comprising combinations of peptides and pharmaceutically acceptable carriers.

Thus, applicant respectfully requests that the enablement rejection be withdrawn.

Claims 1-9 and 11-24 were rejected under 35 U.S.C. 112, first paragraph, for not satisfying the written description requirement. Applicant respectfully disagrees.

Applicant respectfully submits that the peptides presently recited in claim 1, and new independent claims 27 and 29, are disclosed by the present specification at page 4, and, thus, satisfy the written description requirement.

Therefore applicant respectfully requests that the written description rejection be withdrawn.

Claim 14 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for reciting "all states". As claim 14 no longer recites "all states", applicant respectfully requests that the rejection be withdrawn.

Claim 20 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for reciting "implants". Applicant respectfully disagrees.

Applicant respectfully submits that "administration via active ingredient containing implants" would be clear to one of ordinary skill in the art.

Therefore, applicant respectfully requests that the rejection be withdrawn.

Claims 1, 2, 5, and 7-24 were rejected under 35 U.S.C. 102(b) as being anticipated by WO200160794 (WO'794). Applicant respectfully disagrees.

WO'794 discloses a 1-15 amino acid sequence (SEQ ID #8 of WO'794) of the N-terminal of beta-synuclein (e.g. DVFMKGLSMAKEGV). WO'794 discloses that this 1-15 sequence of beta-synuclein interacts with alpha-synuclein at high concentrations, but WO '794 does not specify any shorter sequence that is relevant regarding alpha-synuclein aggregation. WO '794 also discloses an extensive list of possible derivations of the peptide (on pages 35 and 36), which includes acetylation of the N and C-terminal.

Applicant, on the other hand, has shown that various sequences of the whole peptide exhibit different biologic effects, which cause increased neuronal survival but do not correspond to alpha-synuclein aggregation. The present invention is directed to a peptide, which antagonizes the influence of toxic or vitality-damaging noxae of neurodegenerative diseases, consisting of amino acid sequence SMAKEGV (SEQ ID NO: 8), as recited in claims 1, 27 and 29, or peptides that comprise amino acid sequence SMAKEGV (SEQ ID NO: 8), VFMKGLSMAKEGV (SEQ ID NO: 2), FMKGLSMAKEGV (SEQ ID NO: 3), MKGLSMAKEGV (SEQ ID NO: 4), KGLSMAKEGV (SEQ ID NO: 5), GLSMAKEGV (SEQ ID NO: 6), and LSMAKEGV (SEQ ID NO: 7), as recited in claims 1 and 29. The peptides are L-amino and D-amino acids, and are N- and/or C-terminal altered

peptides, as recited in claims 2-9. The peptides are included in compositions with pharmaceutically suitable carriers, as recited in claims 11-24 and 28.

Accordingly, WO'794 does not anticipate the present invention. WO'794 does not disclose any peptide having fewer than the 1-15 amino acids of the sequence DVFMKGLSMAKEGV, as presently recited in independent claims 1, 27 and 29, or compositions comprising those peptides as recited in claims 11-24 and 28.

Moreover, WO'794 fails to disclose a preference for any particular modification of the peptides (e.g. acetylation at the N- or C-terminal positions as recited in claims 7-9). Rather, WO '794 discloses an extensive list of possible derivations, which happens to include acetylation of the N and C-terminal positions.

Thus, for the reasons stated above, applicant believes that WO'794 fails to disclose the present invention with sufficient specificity for the finding of anticipation, and cannot anticipate claim 1 or dependent claims 2, 5 and 7-24, and new claims 27-29.

Therefore, applicant respectfully requests that the anticipation rejection be withdrawn.

Claims 1-3 were rejected under 35 U.S.C. 103(a) as being unpatentable over WO200160794 (WO'794) in view of VOLKMANN et al. (EXS, 1998, 85:87-105) (VOLKMANN). Applicant respectfully disagrees.

WO'794 is offered for the reasons discussed above, and WO'794 fails to disclose or suggest the peptide recited in independent claims 1, 27 and 29 of the present invention.

There would be no motivation to modify WO'794 to arrive at the peptide of claims 1, 27 and 29, since peptide related effects are usually defined by a specific sequence and will be lost upon any change. Applicant has determined that various sequences of the whole peptide exhibit different biologic effects.

The recited peptides cause increased neuronal survival but do not correspond to alpha-synuclein aggregation. WO'794 only points out that amino acid sequence 1-15 of beta-synuclein interacts with alpha-synuclein at high concentrations. WO'794 does not give any information on neurotrophic or neuroprotective effects (e.g. peptides that antagonize the influence of toxic or vitality-damaging noxae of neurodegenerative diseases as recited).

VOLKMANN is offered for the teaching that D-amino acids offer advantages over L-amino acids. However, regardless of the ability of VOLKMANN to teach that for which it is offered, VOLKMANN fails to remedy the deficiencies of WO'794 for reference purposes. VOLKMANN fails to disclose or suggest a peptide SMAKEGV (SEQ ID NO: 8), as recited in claims 1, 27 and 29, or peptides VFMKGLSMAKEGV (SEQ ID NO: 2), FMKGLSMAKEGV (SEQ ID NO: 3), MKGLSMAKEGV (SEQ ID NO: 4), KGLSMAKEGV (SEQ ID NO: 5),

GLSMAKEGV (SEQ ID NO: 6), and LSMAKEGV (SEQ ID NO: 7), as recited in claims 1 and 29.

Thus, the proposed combination fails to render obvious independent claims 1, 27 and 29, and dependent claim 2-3, and applicant respectfully requests that the rejection be withdrawn.

Claims 1 and 4-6 were rejected under 35 U.S.C. 103(a) as being unpatentable over WO200160794 (WO'794) in view of VIGUERA et al. (Protein Science 1999, 8: 1733 - 1742) (VIGUERA) and PRIETO et al. (J. Mol. Biol. 1997, 274: 276 - 288) (PRIETO). Applicant respectfully disagrees.

WO'794 is offered for the reasons discussed above, and WO'794 fails to disclose or suggest the peptide recited in claims 1 and 27 of the present invention.

As discussed previously, there would be no motivation to modify WO'794 to arrive at the peptide of claims 1, 27 and 29, since peptide related effects are usually defined by a specific sequence and will be lost upon any change. Applicant has determined that various sequences of the whole peptide exhibit different biologic effects.

The recited peptides cause increased neuronal survival but do not correspond to alpha-synuclein aggregation. WO'794 only points out that amino acid sequence 1-15 of beta-synuclein interacts with alpha-synuclein at high concentrations. WO'794 does not give any information on neurotrophic or neuroprotective effects (e.g. peptides that antagonize the influence of toxic or

vitality-damaging noxae of neurodegenerative diseases as recited).

VIGUERA is offered for teaching modification of an amino acid in a peptide with proline at N-terminus can enhance the stability of the peptide.

PRIETO is offered for teaching modification of a peptide with proline at C-terminus can enhance the stability of the peptide.

However, neither VIGUERA nor PRIETO are able to remedy the shortcomings of WO'794 for reference purposes, as neither publication discloses or suggests a peptide SMAKEGV (SEQ ID NO: 8), as recited in independent claims 1, 27 and 29, or peptides VFMKGLSMAKEGV (SEQ ID NO: 2), FMKGLSMAKEGV (SEQ ID NO: 3), MKGLSMAKEGV (SEQ ID NO: 4), KGLSMAKEGV (SEQ ID NO: 5), GLSMAKEGV (SEQ ID NO: 6), and LSMAKEGV (SEQ ID NO: 7), as recited in claims 1 and 29.

Therefore, the proposed combination fails to render obvious independent claims 1, 27 and 29, and dependent claim 4-6, and applicant respectfully requests that the rejection be withdrawn.

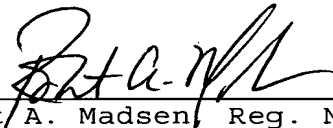
In view of the above, applicant believes that the present application is in condition for allowance at the time of the next Official Action. Allowance and issue on that basis is respectfully requested.

Please charge the fee of \$150 for three extra claims of any type added herewith to Deposit Account No. 25-0120.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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